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Perchlorate Contamination of Drinking Water: Regulatory Issues and Legislative Actions

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Summary

Perchlorate is the main ingredient of solid rocket fuel and has been used mainly by the Department of Defense (DOD), the National Aeronautics and Space Administration (NASA), and related industries. This highly soluble and persistent compound has been disposed of on the ground for decades, and now has been detected in sources of drinking water that serve more than 11 million people. It also has been found in milk and lettuce. Thus, concern has grown regarding the potential health risks of exposure to perchlorate. The Environmental Protection Agency's (EPA's) efforts to make a determination about regulating perchlorate in drinking water have been slowed by uncertainties regarding the health effects of perchlorate exposure at low levels, and because of the need for more research on water treatment technologies. Related issues involve water treatment and environmental cleanup costs, which will depend on the level at which a standard is set. Because of scientific uncertainties and interagency disagreement over the risks of perchlorate, several federal agencies asked the National Research Council (NRC) of the National Academy of Sciences to assess perchlorate's health effects and EPA's draft risk assessment. The NRC issued its report in January 2005, and on February 18, EPA adopted the NRC's recommended safe dose for perchlorate exposure. This report reviews perchlorate issues and will be updated to reflect developments.

Background

Ammonium perchlorate is widely used in solid propellant for rockets and missiles, and other perchlorate salts are used to manufacture various products including fireworks, air bags, and road flares. Uncertainty over perchlorate's health effects has slowed federal and state efforts to establish drinking water standards and environmental cleanup standards for this compound. However, given perchlorate's persistence in water, concern has escalated with its detection in the groundwater or surface water in 33 states. No federal or state drinking water standard has been established for perchlorate, but efforts are underway, and several states have issued public health goals or advisory levels.

Report Documentation Page				Form Approved OMB No. 0704-0188	
Public reporting burden for the collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Washington Headquarters Services, Directorate for Information Operations and Reports, 1215 Jefferson Davis Highway, Suite 1204, Arlington VA 22202-4302. Respondents should be aware that notwithstanding any other provision of law, no person shall be subject to a penalty for failing to comply with a collection of information if it does not display a currently valid OMB control number.					
1. REPORT DATE 23 FEB 2005		2. REPORT TYPE		3. DATES COVERED 00-00-2005 to 00-00-2005	
4. TITLE AND SUBTITLE Perchlorate Contamination of Drinking Water: Regulatory Issues and Legislative Actions				5a. CONTRACT NUMBER	
				5b. GRANT NUMBER	
				5c. PROGRAM ELEMENT NUMBER	
6. AUTHOR(S)				5d. PROJECT NUMBER	
				5e. TASK NUMBER	
				5f. WORK UNIT NUMBER	
7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES) Congressional Research Service, The Library of Congress, 101 Independence Ave, SW, Washington, DC, 20540-7500				8. PERFORMING ORGANIZATION REPORT NUMBER	
9. SPONSORING/MONITORING AGENCY NAME(S) AND ADDRESS(ES)				10. SPONSOR/MONITOR'S ACRONYM(S)	
				11. SPONSOR/MONITOR'S REPORT NUMBER(S)	
12. DISTRIBUTION/AVAILABILITY STATEMENT Approved for public release; distribution unlimited					
13. SUPPLEMENTARY NOTES					
14. ABSTRACT					
15. SUBJECT TERMS					
16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT Same as Report (SAR)	18. NUMBER OF PAGES 6	19a. NAME OF RESPONSIBLE PERSON
a. REPORT unclassified	b. ABSTRACT unclassified	c. THIS PAGE unclassified			

Occurrence. Perchlorate has been used heavily by DOD and its contractors, and perchlorate contamination of ground and surface water has been found most often near weapons and rocket fuel manufacturing facilities and disposal sites, research facilities, and military bases.¹ Fireworks and other manufacturing facilities also have been sources of contamination. Regulators were aware of contamination in California and Nevada in the 1980s; however, before 1997, perchlorate could not be detected at concentrations below 400 parts per billion (ppb). In 1997, the California Department of Health Services developed a new analytical method for monitoring perchlorate that lowered the detection limit to 4 ppb. This development prompted several states to test for perchlorate. Within two years, perchlorate had been detected in drinking water sources for more than 11 million people in the Southwest and in surface or ground water in scattered locations across the United States.² The contamination has most often been found in wells; however, perchlorate has been detected at low levels in the Colorado River, which is a major source of drinking water and irrigation water in California, Nevada, and Arizona.³ Perchlorate also has been detected in dairy milk from California and Texas, and a source of contamination is thought to have been the water used to irrigate the alfalfa crops that were consumed by dairy cows. Perchlorate also occurs naturally, as it does in West Texas, and it is present in organic fertilizer from Chile, which has been used on organic crops.

In 1999, EPA required drinking water monitoring for perchlorate under the Unregulated Contaminant Monitoring Rule (UCMR) to determine the frequency and levels at which perchlorate is present in public water supplies nationwide. The regulation required monitoring by all water systems serving more than 10,000 persons and by a representative sample of smaller systems. In 2004, EPA reported that perchlorate has been detected in public water systems in 24 states and Puerto Rico.⁴ The agency also reported perchlorate contamination at 65 DOD facilities, 7 other federal facilities, and 37 private sites. In sampling done by California water systems, perchlorate has been detected in 365 sources of drinking water that supply 94 public water systems.⁵ A recent American Water Works Association perchlorate study found the compound in 26 states and Puerto Rico.

¹ U.S. Army Center for Health Promotion and Preventive Medicine, Directorate of Environmental Health Engineering, *Perchlorate in Drinking Water*, Aberdeen Proving Ground, MD. This document notes that perchlorate has a short shelf life as an effective propellant and must be replaced periodically within the DOD's missile and rocket inventory. Thus, DOD has disposed of large volumes of perchlorate since the 1950s. Also, the detonation of rockets, missiles, and fireworks leaves residual perchlorate in the affected areas.

² U.S. Environmental Protection Agency, *Region 9 Perchlorate Update*, June 1999, p. 1.

³ A key source of perchlorate in the Colorado River has been the Kerr McGee Chemical Plant in Nevada, where perchlorate production began in 1951. Since 1997, the state of Nevada and the U.S. EPA have worked with Kerr McGee to control the source of perchlorate releases. Since 2002, perchlorate has been below 6 ppb. In 2004, 9 of 12 monthly samples had non-detectable (i.e., less than 4 ppb) levels of perchlorate. U.S. Environmental Protection Agency, Region 9, *Perchlorate Monitoring Results: Henderson, Nevada to the Lower Colorado River*, Dec. 2004.

⁴ U.S. Environmental Protection Agency, *Federal Facilities Restoration and Reuse: Known Perchlorate Releases in the U.S. -Sept. 23, 2004*, available at [http://www.epa.gov/fedfac/documents/perchlorate_links.htm#occurrences], visited February 23, 2005.

⁵ California Department of Health Services, *Perchlorate in California Drinking Water: Monitoring Update*, December 7, 2004. For detailed monitoring results, see [<http://dhs.ca.gov/ps/ddwem/chemicals/perchl/monitoringupdate.htm>], visited February 23, 2005.

Health Effects. Perchlorate is known to disrupt the uptake of iodine in the thyroid, and health effects associated with perchlorate exposure are expected to be similar to those caused by iodine deficiency.⁶ Iodine deficiency decreases the production of thyroid hormones, which help regulate the body's metabolism and growth. A key concern is that impairment of thyroid function in pregnant women can affect fetuses and infants and can result in delayed development and decreased learning capability. Various human studies indicate that thyroid changes occur in humans at significantly higher concentrations of perchlorate than the amounts typically observed in water supplies.⁷ Studies have not directly measured the impact of perchlorate on human metabolism and growth. (Health effects studies are discussed further in section below on EPA regulation of perchlorate.)

Federal Responses to Perchlorate Contamination

Various federal, state, tribal, and local government agencies have been examining issues related to perchlorate contamination for nearly a decade. A federal interagency perchlorate working group was convened in 2002, to discuss perchlorate risk assessment, research, and regulatory issues. Members of this group include DOD; NASA; EPA; the Department of Energy; and, within the Executive Office of the President, the Office of Science and Technology Policy, the Council on Environmental Quality, and the Office of Management and Budget. DOD, EPA, and the Food and Drug Administration are among the federal agencies that have been assessing perchlorate contamination and occurrence.

Department of Defense. The DOD, which has the greatest number of identified sites with perchlorate contamination, has spent \$26 million on developing and testing perchlorate treatment technologies and is funding several more demonstration projects during FY2005. Perchlorate cleanup is proceeding at several sites; however, DOD's general policy is to remediate sites to meet drinking water standards. In the absence of a perchlorate standard, this approach has been problematic for communities that are experiencing perchlorate contamination of their water supplies.

In September 2003, the DOD adopted a perchlorate sampling policy that includes sampling on Base Realignment and Closure (BRAC) properties. However, DOD was criticized by Members of Congress, communities, and states for not evaluating other DOD sites. In October 2004, DOD and the California EPA adopted a procedure for prioritizing perchlorate sampling efforts at DOD facilities in California. The procedure document is intended to provide guidance on the steps that the state and DOD will take to identify and prioritize the investigation of areas on military sites where perchlorate has likely been

⁶ California Environmental Protection Agency, Office of Environmental Health Hazard Assessment, *Public Health Goal for Perchlorate*, March 2004, pp. 1-2. In March 2004, California published a final public health goal (PHG) of 6 ppb for perchlorate. A PHG is set at a level determined to pose no significant risk to individuals, including sensitive groups (i.e., infants, pregnant women, and individuals with iodine deficiency). California officials will use the public health goal to establish an enforceable drinking water standard, which must be set as close to the goal as is economically and technologically feasible.

⁷ Michael A. Kelsh et al., "Primary Congenital Hypothyroidism, Newborn Thyroid Function, and Environmental Perchlorate Exposure Among Residents of a Southern California Community," *Journal of Occupational Environmental Medicine*, 2003, p. 1117.

released near drinking water sources. DOD has stated that it will characterize and respond to identified problems under its existing environmental response programs.

A key issue for DOD concerns the potential perchlorate cleanup cost, which will depend largely on any standards set by EPA and/or a state. This is because federal and state drinking water standards are used as cleanup standards, specifically at Superfund sites, but in other cases as well. Similarly, public water suppliers that will have to treat their water to meet federal and state drinking water standards are interested in seeing that a standard is set at a level that assures public health protection, but is not so strict that added costs would be incurred without providing any further public health benefits.

EPA Regulation of Perchlorate. EPA has taken steps toward establishing a drinking water standard for perchlorate, but has not yet made a determination to regulate perchlorate. In 1997, when a better detection method became available for perchlorate and water monitoring increased, scientific information for perchlorate was extremely limited. In 1998, EPA placed perchlorate on the list of contaminants that are candidates for regulation, but concluded that information was insufficient at that time to make a determination as to whether perchlorate should be regulated under the Safe Drinking Water Act (SDWA). The agency listed perchlorate as a priority for further research on health effects and treatment technologies, and as a priority for collecting occurrence data.

Perchlorate Risk Assessment. In 1992, and again in 1995, EPA issued draft reference doses (RfDs) for perchlorate exposure that would be expected to protect against any health threats. An RfD is an estimate (with uncertainty spanning perhaps an order of magnitude) of a daily oral exposure that is likely to be without appreciable risk of adverse non-cancer effects during a lifetime. In developing an RfD, EPA incorporates factors to account for sensitive subpopulations, study duration, inter- and intraspecies variability, and data gaps. The resulting draft RfD range of 0.0001 to 0.0005 milligrams per kilogram (mg/kg) body weight per day would be equivalent to a drinking water level of 4 ppb-18 ppb. EPA takes the RfD into consideration when setting a drinking water standard. The agency also must consider cost, the capabilities of monitoring and treatment technologies, and other sources of perchlorate exposure, such as food.

EPA continued to assess perchlorate risks, and its 1999 draft risk characterization resulted in a human risk benchmark of 0.0009 mg/kg per day (with a 100-fold uncertainty factor), which would convert to a drinking water equivalent level of 32 ppb. However, EPA determined that the available health effects and toxicity database was inadequate for risk assessment. In 1999, EPA issued an *Interim Assessment Guidance for Perchlorate*, which recommended that EPA risk assessors and risk managers use the standing reference dose range of 4-18 ppb for perchlorate-related assessment activities.

In 2002, EPA completed a draft risk assessment for perchlorate that concluded that the potential human health risks of perchlorate exposures include effects on the developing nervous systems and thyroid tumors, based on rat studies that observed benign tumors and adverse effects in fetal brain development. The document included a draft RfD of 0.00003 mg/kg per day, which translated to a drinking water equivalent level of 1 ppb. This draft document has been controversial, both for its implications for cleanup costs and for science policy reasons. For example, comments from some expert peer reviewers and stakeholders expressed concern about EPA's use of a new risk assessment approach, and the selection of certain rat studies as the basis for conducting the risk assessment.

In 2003, EPA affirmed the 1999 Interim Guidance that recommended continuing the use of the 1992 and 1995 draft reference doses for perchlorate assessment activities. Based on this RfD range (0.0001 to 0.0005 mg/kg per day), clean-up levels range from 4 ppb to 18 ppb. The 1999 guidance remains the applicable guidance, until replaced by new guidance that will be based on the finalized risk assessment and new RfD.

In an effort to resolve some of the uncertainty and debate over perchlorate's health effects and EPA's 2002 assessment, the interagency perchlorate working group asked the National Research Council (NRC) to review the science for perchlorate and EPA's draft risk assessment. The NRC was asked to comment and make recommendations.

NRC Perchlorate Report. The NRC Committee to Assess the Health Implications of Perchlorate Ingestion issued its review on January 10, 2005. Based on its scientific findings, this independent expert committee suggested several changes to EPA's draft risk assessment. The committee determined that, because of major differences between rats and humans, studies in rats are of limited use for quantitatively assessing human health risk associated with perchlorate exposure. Although the committee agreed that thyroid tumors found in a few rats were likely perchlorate treatment-related, it concluded that perchlorate exposure is unlikely to lead to thyroid tumors in humans. The committee noted that, unlike rats, humans have multiple mechanisms to compensate for iodide deficiency and thyroid disorders, and that hypothyroidism occurs only if daily iodide intake is less than about 10%-20% of average U.S. intake. Also, the NRC found flaws in the design and methods used in the rat studies. The committee concluded that the animal data selected by EPA should not be used as the basis of the risk assessment.

The committee also reviewed EPA's risk assessment model. It thought that EPA's model for perchlorate toxicity represented the possible early sequence of events after exposure, but did not think that the model provided an accurate representation of possible outcomes after changes in thyroid hormone production. Also, the committee disagreed with EPA's definition of a change in thyroid hormone level as an adverse effect. Rather, the NRC defined transient changes in serum thyroid hormone as biochemical events that might precede adverse effects, and identified hypothyroidism as the first adverse effect.

Because of research gaps regarding perchlorate's potential effects following changes in thyroid hormone production, the committee made the unusual recommendation that EPA use a *nonadverse effect* (i.e., the inhibition of iodide uptake by the thyroid in humans) rather than an adverse effect as the basis for the risk assessment. The committee explained that "[i]nhibition of iodide uptake is a more reliable and valid measure, it has been unequivocally demonstrated in humans exposed to perchlorate, and it is the key event that precedes all thyroid-mediated effects of perchlorate exposure."⁸ Based on the use of this conservative point of departure, the reliance on human studies, and the use of an uncertainty factor of 10 (for intraspecies differences), the NRC's recommendations lead to an RfD of 0.0007 mg/kg per day. The committee concluded that this RfD should protect the most sensitive population (i.e., the fetuses of pregnant women who might have hypothyroidism or iodide deficiency) and noted that the RfD is supported by clinical

⁸ National Research Council, *Health Implications of Perchlorate Ingestion*, Committee to Assess the Health Implications of Perchlorate Ingestion, National Academy of Sciences, Jan. 2005, p.9.

studies, occupational and environmental epidemiologic studies, and studies of long-term perchlorate administration to patients with hyperthyroidism.⁹

On February 18, 2005, EPA adopted the NRC recommended reference dose, and the agency's Superfund office plans to issue new cleanup guidance based on this RfD. The RfD translates to a drinking water equivalent level (DWEL) of 24.5 ppb. The DWEL is the concentration of a contaminant in drinking water that would have no adverse effect and includes a margin of safety. It also is based on the assumption that all of the exposure would come from drinking water. Thus, if EPA were to develop a drinking water standard for perchlorate, it would adjust the DWEL to account for other sources of exposure.

Food and Drug Administration. During 2004, the FDA collected 500 samples of foods, including various vegetables, milk, and bottled water, to determine the presence and levels of perchlorate in food. Samples were taken in areas where water sources are believed to be contaminated with perchlorate. In November 2004, the FDA posted its sampling results. Perchlorate was detected in roughly 90% of lettuce samples (average levels ranged from 11.9 ppb to 7.7 ppb for different lettuce types in 4 states), and in 101 of 104 milk samples collected at retail locations (with an average level of 5.7 ppb across 14 states).¹⁰ Perchlorate was detected in two bottled water samples at roughly 0.5 ppb. The FDA plans to collect and analyze another 750 samples during FY2005. FDA's research is relevant to EPA's standard-setting efforts, because EPA would take into account exposures to perchlorate from food and other sources when establishing a drinking water standard. Specifically, if other exposure sources are significant, EPA would set a stricter drinking water standard to account for those exposures.

Congressional Actions

Interest in perchlorate contamination and regulation grew in the 108th Congress, and several perchlorate-related provisions were enacted. The National Defense Authorization Act for FY2004 (P.L. 108-136) required DOD to provide for a health study regarding exposure to perchlorate in drinking water. (The study is expected in June 2005.) The conference report for the Military Construction Appropriations Act for FY2004 (P.L. 108-132) directed DOD to submit a report identifying sources of perchlorate on BRAC properties and plans to remediate these sites. (DOD submitted its report in July 2004.) The conference report for the DOD appropriations for FY2004 (P.L. 108-87) directed DOD to study perchlorate contamination of groundwater in the Southwest. The National Defense Authorization Act for FY2005 (P.L. 108-375) included a "Sense of Congress" that DOD should develop a plan to remediate contamination, continue remediating sites where contamination poses a serious health threat, and continue evaluating sites in the absence of a drinking water standard. Congress also funded perchlorate cleanup activities in several communities through appropriations acts.

In the 109th Congress, perchlorate continues to receive attention. H.R. 213 has been introduced to require EPA to issue a drinking water standard for perchlorate by July 2007.

⁹ Ibid. p. 10.

¹⁰ U.S. Food and Drug Administration, *Exploratory Data on Perchlorate in Food*, Nov. 2004.